K090336

EXHIBIT #3

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Applicant:**
   Sunmax Enterprise Shanghai Co., Ltd
   No.2 New Industrial Area, Zhu Hang Zhen
   Jin Shan Xian, Shanghai, China

   JUL - 1 2009

2. **Manufacturer:**
   Sunmax Enterprise Shanghai Co., Ltd
   No.2 New Industrial Area, Zhu Hang Zhen
   Jin Shan Xian, Shanghai, China

3. **Submitter:**
   Mr. Jigar Shah
   Official Correspondent for
   Sunmax Enterprise Shanghai Co., Ltd

4. **Address:**
   mdi Consultants, Inc.
   55 Northern Blvd., Suite 200
   Great Neck, New York 11021
   Tel: 516-482-9001
   Fax: 516-482-0186
   jigar@mdiconsultants.com

5. **Trade/proprietary Name:**
   Sunmax Enterprise Shanghai Co Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs.

6. **Common Names:**
   POWDER-FREE Patient Examination Glove

7. **Classification name:**
   Patient Examination Glove

8. **Classification number:**
   21 CFR 880.6250

9. **Device Description:**
Sunmax Enterprise Shanghai Co Powder free blue Nitrile Examination Glove is a class II device having product code 80LZA. It is a disposable device that meets all requirements of ASTM D 631900a-05 and is tested with chemotherapy drugs.

10. **Intended Use:**
A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier.

11. **Substantial Equivalence Discussion:**

A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is substantially equivalent to the predicate devices.

Characteristic and parameters	**Sunmax Enterprise Shanghai Co., LTD (New Device)**	**Shanghai China Star Corp (K) 071072**	**MEDLINE INDUSTRIES, INC (K) 040841**	**Substantial Equivalence (SE)**
Product Code	LZA	LZA	LZA	
Intended Use	A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier	A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier	Medline Powder-Free Blue Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	SE
Width (size medium)	89mm	92mm	92mm	Minor difference

Overall length	240mm	240mm	240mm	SE
Palm thickness	0.12mm	0.17mm	0.17mm	Minor difference
Finger thickness	0.12mm	0.18mm	0.18mm	
Tensile strength pre aging min	18mpa	21mpa	21mpa	
Tensile strength after aging min	18mpa	16mpa	16mpa	
Ultimate elongation pre aging min	600	500	500	
Ultimate elongation after aging min	570	500	500	
Meets Biocompatibility	Yes	Yes	Yes	SE
Duration of bio-compatibility	Limited	Limited	Limited	
Skin irritation test	Passes	Passes	Passes	
Dermal sensitization	Passes	Passes	Passes	
Residual powder test	Passes	Passes	Passes	

12. Summary of Testing:

	Test	**Results**
a.	Dermal Sensitization Test	Passes
b.	Primary Skin irritation	Passes
c.	Permeation testing per ASTM D 6978-05	Passes
d.	Iodine Test	Passes
e.	Tensile strength	Gloves meets the requirements of ASTM D63 19-00a.
f.	Barrier strength	Gloves meets the requirements of ASTM D63 19-00a.

The standards used by Sunmax Enterprise Shanghai Co to determine substantial equivalence are based on ASTM D 631900a-2005. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, pinholes at AQL 2.5

There are no special labeling claims and we do not claim our gloves to be hypoallergenic.

13. Conclusion:

Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs performance was equivalent to any other conventional method evaluated. Our evaluation concluded that our device raises no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Sunmax Enterprise Shanghai Company, Limited
C/O Mr. Jigar Shah
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K090336
Trade/Device Name: Powder-Free, Blue, Nitrile Examination Gloves Tested with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: June 25, 2009
Received: June 30, 2009

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #1

Indications for Use

510(k) Number (if known): K090336

Applicant: Sunmax Enterprise Shanghai Co Ltd

Device Name: Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs.

Indications for Use:
A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

Chemotherapy drugs with their breakthrough times:

Dacarbazine	240 minutes
Cyclophosphamide(Cytoxan)	240 minutes
Doxorubicin Hydrochloride	240 minutes
Fluorouracil	240 minutes
Cisplatin	240 minutes
Etoposide (Toposar)	240 minutes
Paclitaxel (Taxol)	240 minutes
Thio-Tepa	23.3 minutes
Carmustine	18.7 minutes

Prescription Use_____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shuh A Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090336